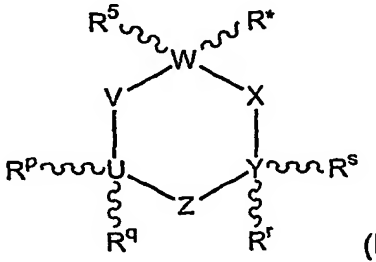
CLAIMS

1. An aqueous based composition for pharmaceutical use comprising an aqueous vehicle and a Cyclohexylamine or Aminoadamantane derivative of the formula (I),



(I)

wherein R^* is $-(A)_n-(CR^1R^2)_m-NR^3R^4$,

n+m = 0, 1, or 2,

A is selected from the group consisting of linear or branched lower alkyl (C_1-C_6),linear or branched lower alkenyl (C_2-C_6), and linear or branched lower alkynyl (C_2-C_6),

R^1 and R^2 are independently selected from the group consisting of hydrogen, linear or branched lower alkyl (C_1-C_6), linear or branched lower alkenyl (C_2-C_6), linear or branched lower alkynyl (C_2-C_6) aryl, substituted aryl and arylalkyl,

R^3 and R^4 ~~are independently~~ selected from the group consisting of hydrogen, linear or branched lower alkyl (C_1-C_6), linear or branched lower alkenyl (C_2-C_6), and linear or branched lower alkynyl (C_2-C_6), or together form alkylene (C_2-C_{10}) or alkenylene (C_2-C_{10}) or together with the N form a 3-7-membered azacycloalkane or azacycloalkene, including substituted (alkyl (C_1-C_6), alkenyl (C_2-C_6)) 3-7-membered azacycloalkane or azacycloalkene; or independently R^3 or R^4 may combine with R^p, R^q, R^r, or R^s to form an alkylene chain $-CH(R^6)-(CH_2)_t-$,

wherein t = 0 or 1 and R^6 is selected from the group consisting of hydrogen, linear or branched lower alkyl (C_1-C_6), linear or branched lower alkenyl (C_2-C_6), linear or branched lower alkynyl (C_2-C_6), aryl, substituted aryl and arylalkyl; or independently R^3 or R^4 may combine with R^5 to form an alkylene chain represented by the formula $-CH_2-CH_2-CH_2-(CH_2)_t-$, or an alkenylene chain represented by the formulae $-CH=CH-CH_2-(CH_2)_t-$, $-CH=C=CH-(CH_2)_t-$ or $-CH_2-CH=CH-(CH_2)_t-$, wherein t = 0 or 1;

R^5 is independently selected from the group consisting of hydrogen, linear or branched lower alkyl (C_1-C_6), linear or branched lower alkenyl (C_2-C_6), and linear or branched lower alkynyl (C_2-C_6), or R^5 combines with the carbon to which it is attached and the next adjacent ring carbon to form a double bond,

R^p, R^q, R^r, and R^s, are independently selected from the group consisting of hydrogen, linear or branched lower alkyl (C_1-C_6), linear or branched lower alkenyl (C_2-C_6), linear or branched lower alkynyl (C_2-C_6), cycloalkyl (C_3-C_6) and aryl, substituted aryl and arylalkyl or R^p, R^q, R^r, and R^s independently may form a double bond with U or with Y or to which it is attached, or R^p, R^q, R^r, and R^s may combine together to represent a lower alkylene $-(CH_2)_x-$ or a lower alkenylene bridge wherein x is 2-5, inclusive, which alkylene bridge may, in turn, combine with R^5 to form an additional lower alkylene $-(CH_2)_y-$ or a lower alkenylene bridge, wherein y is 1-3, inclusive,

-the symbols U, V, W, X, Y, Z represent carbon atoms;

including the respective optical isomers, diastereomers, polymorphs, enantiomers, hydrates, pharmaceutically acceptable salts, and mixtures;

wherein the composition is optionally free of preservatives.

2. The composition of claim 1, wherein the concentration of the Cyclohexylamine or Aminoadamantane derivative is at least about 1 mg/mL.

3. The composition of claim 1, wherein the concentration of the Cyclohexylamine or Aminoadamantane derivative has an overall strength of about 2 mg/mL.

4. The composition of claim 1, wherein the concentration of the Cyclohexylamine or Aminoadamantane derivative has an overall strength of about 4 mg/mL.

5. The composition of claim 1, wherein the concentration of the Cyclohexylamine or Aminoadamantane derivative has an overall strength of about 5 mg/mL.

6. The composition of claim 1, wherein the concentration of the Cyclohexylamine or Aminoadamantane derivative has an overall strength of about 10 mg/mL.

7. The composition of claim 1, wherein the concentration of the Cyclohexylamine or Aminoadamantane derivative has an overall strength of about 20 mg/mL.

8. The composition of claim 1, wherein the Cyclohexylamine or Aminoadamantane derivative is memantine or a pharmaceutically acceptable salt thereof.

9. The composition of claim 8, wherein the Cyclohexylamine or Aminoadamantane derivative is memantine hydrochloride.

10. The composition of claim 8, wherein the concentration of memantine or of the pharmaceutically acceptable salt thereof is in the range from about 1 mg/mL to about 50 mg/mL.

11. The composition of claim 10, wherein the concentration of memantine or of the pharmaceutically acceptable salt thereof is about 10 mg/mL.

12. The composition of claim 1, wherein the Cyclohexylamine or Aminoadamantane derivative is neramexane or a pharmaceutically acceptable salt thereof.

13. The composition of claim 12, wherein the Cyclohexylamine or Aminoadamantane derivative is neramexane mesylate.

14. The composition of claim 12, wherein the concentration of neramexane or of the pharmaceutically acceptable salt thereof is in the range from about 2 mg/mL to about 100 mg/mL.

15. The composition of claim 14, wherein the concentration of neramexane or of the pharmaceutically acceptable salt thereof is in the range from about 5 mg/mL to about 10 mg/mL.

16. The composition of claim 1, wherein the aqueous vehicle is purified water, USP.

17. The composition of claim 1, optionally comprising one or more sweeteners present in an amount ranging from about 10 mg/ml to about 500 mg/ml.

18. The composition of claim 17, wherein the sweetener is selected from the group consisting of sorbitol, sucrose, saccharin sodium, aspartame and N & A Flavor Enhancer.

19. The composition of claim 17, wherein the sweetener is sorbitol.

20. The composition of claim 1, optionally comprising a solubilizer selected from the group consisting of propylene glyco, polyethylene glycol, and glycerin present in an amount ranging from about 8% to about 12% w/v

21. The composition of claim 20, wherein the solubilizer is glycerin.

22. The composition of claim 21, wherein the glycerin is present in an amount ranging from about 8% w/v to about 12% w/v solution.

23. The composition of claim 1, further comprising one or more excipients selected from the group consisting of flavors, flavor enhancers; taste masking agents, thickeners, stabilizers, and crystallization inhibitors.

24. The composition of claim 23, wherein the flavor is selected from the group consisting of natural peppermint #104, artificial cherry #10641,

artificial grape #255, orange N&A 583K and artificial grape bubble gum # 998.

25. The composition of claim 23, wherein the flavor is present in a concentration ranging from about 0.05% to about 2.0%.

26. The composition of claim 1, further comprising another active compound effective in the management of CNS-related conditions or diseases, wherein said active compound is not an NMDA receptor antagonist selected from compounds of the formula (I).

27. The composition of claim 1, further comprising a buffer to adjust pH of the solution.

28. The composition of claim 27, wherein the buffer is selected from the group consisting of citric acid, sodium citrate, acetic acid, sodium acetate, sodium phosphate, and combinations of two or more of the foregoing.

29. The composition of claim 27, wherein the buffer is a combination of citric acid and sodium citrate.

30. The composition of claim 27, wherein the buffer is present an amount ranging from about 1 mg/ml to about 10 mg/ml.

31. The composition of claim 27, wherein the pH is adjusted to between about 4.5 to about 6.5.

32. The composition of claim 27, wherein the pH is adjusted to about 5.5.

33. The composition of claim 1 which is preservative free.

34. The composition of claim 1, further comprising a preservative, wherein the concentration of the preservative is less than the concentration required to effectively preserve the corresponding placebo composition.

35. The composition of claim 1, further comprising a preservative in an amount ranging from about 0.05% to about 2.0% w/v.

36. The composition of claim 35, further comprising a preservative in an amount ranging from about 0.1% to about 1.0% w/v.

37. The composition of claim 35, wherein the preservative is present in an amount of about 0.1% w/v.

38. The composition of claim 34, wherein the preservative is selected from the group consisting of methyl paraben, propyl paraben, sodium benzoate, potassium sorbate, and combinations of two or more of the foregoing.

39. A container comprising a plurality of doses of a Cyclohexylamine or Aminoadamantane derivative selected from compounds of the formula (I), wherein the Cyclohexylamine or Aminoadamantane derivative is formulated as a composition of claim 1.

40. The container of claim 39, wherein the volume of the composition is in the range from about 5 mL to about 1,000 mL.

41. The container of claim 39, further comprising a means for measuring a volume in the range from about 0.5 to about 10 mL.

42. A composition of claim 1 comprising

    a. Memantine HCl
    b. Purified Water, USP, QS.

43. A composition of claim 1 comprising

    a. Memantine HCl
    b. Sorbitol solution, USP 70%
    c. Purified Water, USP, QS.

44. A composition of claim 1 comprising

a. Neramexane mesylate
b. Purified Water, USP, QS.

45. A composition of claim 1 comprising

a. Neramexane mesylate
b. Sorbitol solution, USP 70%
c. Citric Acid, USP
d. Sodium Citrate, USP and
e. Purified Water, USP, QS.

46. A composition of claim 1 comprising:

a. Memantine HCl, 0.20% w/v;
b. Sorbitol solution, USP 70%, 30.0% w/v;
c. Methylparaben NF, 0.1 % w/v;
d. Propylparaben NF, 0.01% w/v;
e. Propylene Glycol, USP, 2.50% w/v;
f. Glycerin, USP; 10.0% w/v;
g. Natural Peppermint Flavor #104, 0.05% w/v;
h. Citric Acid, USP 0.19% w/v;
i. Sodium Citrate, USP 0.88% w/v; and
j. Purified Water, USP, QS.

47. A composition of claim 1 comprising:

a. Memantine HCl, 0.40% w/v;
b. Sorbitol solution, USP 70%, 30.0% w/v;
c. Methylparaben NF, 0.1 % w/v;
d. Propylparaben NF, 0.01% w/v;
e. Propylene Glycol, USP, 2.50% w/v;
f. Glycerin, USP; 10.0% w/v;
g. Natural Peppermint Flavor #104, 0.05% w/v;
h. Citric Acid, USP 0.19% w/v;
i. Sodium Citrate, USP 0.88% w/v; and

j. Purified Water, USP, QS.

48. A composition of claim 1 comprising:
    a. Neramexane mesylate 0.20% w/v;
    b. Sorbitol solution, USP 70%, 30.0% w/v;
    c. Methylparaben, NF 0.1 % w/v;
    d. Propylparaben, NF 0.01% w/v;
    e. Propylene Glycol, USP, 2.50% w/v;
    f. Glycerin, USP; 10.0% w/v;
    g. Natural Peppermint Flavor #104 0.5% w/v;
    h. Citric Acid, USP 0.19% w/v;
    i. Sodium Citrate, USP 0.88% w/v;
    j. Purified Water, USP, QS; and
    k. Prosweet N & A FL Enhancer, 1% w/v.

49. A composition of claim 1 comprising:
    a. Neramexane HCl 0.20% w/v;
    b. Sorbitol solution, USP 70%, 30.0% w/v;
    c. Methylparaben, NF 0.1 % w/v;
    d. Propylparaben, NF 0.01% w/v;
    e. Propylene Glycol, USP, 2.50% w/v;
    f. Glycerin, USP; 10.0% w/v;
    g. Natural Peppermint Flavor #104 0.5% w/v;
    h. Citric Acid, USP 0.19% w/v;
    i. Sodium Citrate, USP 0.88% w/v;
    j. Purified Water, USP, QS; and
    k. Prosweet N & A FL Enhancer, 1% w/v.

50. A composition of claim 1 comprising:
    a. Neramexane mesylate 0.5% w/v;
    b. Sorbitol solution, USP 70%, 30.0% w/v;
    c. Methylparaben, NF 0.1 % w/v;
    d. Propylparaben, NF 0.01% w/v;
    e. Propylene Glycol, USP, 2.50% w/v;
    f. Glycerin, USP; 10.0% w/v;

g. Natural Peppermint Flavor #104 0.5% w/v;
h. Citric Acid, USP 0.19% w/v;
i. Sodium Citrate, USP 0.88% w/v;
j. Purified Water, USP, QS; and
k. Prosweet N & A FL Enhancer, 1% w/v.

51. A composition of claim 1 comprising:
a. Neramexane HCl 0.5% w/v;
b. Sorbitol solution, USP 70%, 30.0% w/v;
c. Methylparaben, NF 0.1 % w/v;
d. Propylparaben, NF 0.01% w/v;
e. Propylene Glycol, USP, 2.50% w/v;
f. Glycerin, USP; 10.0% w/v;
g. Natural Peppermint Flavor #104 0.5% w/v;
h. Citric Acid, USP 0.19% w/v;
i. Sodium Citrate, USP 0.88% w/v;
j. Purified Water, USP, QS; and
k. Prosweet N & A FL Enhancer, 1% w/v.

52. A composition of claim 1 comprising:
a. Neramexane mesylate 1.0% w/v;
b. Sorbitol solution, USP 70%, 30.0% w/v;
c. Methylparaben, NF 0.1 % w/v;
d. Propylparaben, NF 0.01% w/v;
e. Propylene Glycol, USP, 2.50% w/v;
f. Glycerin, USP; 10.0% w/v;
g. Natural Peppermint Flavor #104 0.5% w/v;
h. Citric Acid, USP 0.19% w/v;
i. Sodium Citrate, USP 0.88% w/v;
j. Purified Water, USP, QS; and
k. Prosweet N & A FL Enhancer, 1% w/v.

53. A composition of claim 1 comprising:
a. Neramexane HCl 1.0% w/v;
b. Sorbitol solution, USP 70%, 30.0% w/v;
c. Methylparaben, NF 0.1 % w/v;

d. Propylparaben, NF 0.01% w/v;
e. Propylene Glycol, USP, 2.50% w/v;
f. Glycerin, USP; 10.0% w/v;
g. Natural Peppermint Flavor #104 0.5% w/v;
h. Citric Acid, USP 0.19% w/v;
i. Sodium Citrate, USP 0.88% w/v;
j. Purified Water, USP, QS;
k. Prosweet N & A FL Enhancer, 1% w/v.

54. A composition of claim 1 comprising:
a. Neramexane mesylate 2.0% w/v;
b. Sorbitol solution, USP 70%, 30.0% w/v;
c. Methylparaben, NF 0.1 % w/v;
d. Propylparaben, NF 0.01% w/v;
e. Propylene Glycol, USP, 2.50% w/v;
f. Glycerin, USP; 10.0% w/v;
g. Natural Peppermint Flavor #104 0.5% w/v;
h. Citric Acid, USP 0.19% w/v;
i. Sodium Citrate, USP 0.88% w/v;
j. Purified Water, USP, QS; and
k. Prosweet N & A FL Enhancer, 1% w/v.

55. A composition of claim 1 comprising:
a. Neramexane HCl 2.0% w/v;
b. Sorbitol solution, USP 70%, 30.0% w/v;
c. Methylparaben, NF 0.1 % w/v;
d. Propylparaben, NF 0.01% w/v;
e. Propylene Glycol, USP, 2.50% w/v;
f. Glycerin, USP; 10.0% w/v;
g. Natural Peppermint Flavor #104 0.5% w/v;
h. Citric Acid, USP 0.19% w/v;
i. Sodium Citrate, USP 0.88% w/v;
j. Purified Water, USP, QS; and
k. Prosweet N & A FL Enhancer, 1% w/v.